DEPARTMENT OF HEALTH & HUMAN SERVICES



National Institutes of Health Bethesda, Maryland 20892

August 22, 2001

TO:

Addressees

FROM:

Deputy Director for Intramural Research, NIH

SUBJECT:

Communicating Animal Care and Use Concerns within the

NIH Intramural Research Program

The purpose of this memorandum is to reaffirm my 1996 commitment to maintain full and open communications regarding animal care and use in the NIH Intramural Research Program (IRP). I feel strongly that a clear and thorough understanding of NIH management and administrative practices by all IRP staff will enhance our research environment.

The care and use of animals in biomedical research carries with it the requirement to comply with Federal laws, regulations and policies. That collection of regulations and policies governs all aspects of our animal-related activities, including our relationships with other NIH employees and contractors.

I encourage everyone in the NIH IRP who has concerns regarding any aspect of the care and use of animals in research at NIH to voice that concern. In the animal facilities, each facility veterinarian has the authority and responsibility for ensuring compliance with all animal care and use standards and is the appropriate individual to receive initial concerns related to that facility. The Chair of the Institute/Center (IC) Animal Care and Use Committee (ACUC) is the most appropriate individual to field concerns about animal research procedures or techniques, especially those that are performed in laboratory settings. Concerns not directly related to a particular facility or IC, or not appropriately dealt with at a local level, should be addressed to the Office of Animal Care and Use (OACU), Office of Intramural Research, or directly to me. Concerns received by any of these individuals or offices will be reviewed and corrective measures instituted as appropriate.

The Director, OACU, assists me, as Institutional Official, in assessing all allegations. I determine the level at which the allegation should be pursued, including involving the NIH Ombudsman, who can conduct an immediate assessment of the alleged conditions, as outlined in the NIH Animal Research Advisory Committee Guidelines (http://oacu.od.nih.gov/ARAC/ombdsmn.htm). If necessary, I will ask the ACUC Chair to assemble an investigative team made up of scientists, veterinarians and other administrative or management officials to assure a balanced and thorough assessment of the allegation. Teams are made up of individuals with expertise in biomedical research, personnel management, and/or other specialty fields deemed appropriate to the situation at hand. Alternatively, I have the option to conduct investigations out of my immediate office.

An incident or finding that involves any of the following must be reported to the responsible IC ACUC and then to the OACU as quickly as possible. That initial reporting should include a summary of the incident, the initial corrective steps to be taken by the ACUC and/or the IC, and the plan of action. It is imperative that this initial reporting be accomplished within 24 hours.

Reportable incidents include:

1. Animal death, animal injury, or compromise of animal well-being has occurred due to negligence or inappropriate behavior by anyone in NIH-managed facilities;

- 2. Any serious or continuing noncompliance with PHS Policy;
- 3. Any serious deviation from the provisions of the Guide;
- 4. Suspension of an activity by any IC ACUC.

If you are uncertain about whether an incident or activity should be reported, please report it.

Upon notification of these incidents by OACU and following my subsequent review of the results of related investigations, I will report fully any noncompliant activities and the resultant corrective actions to the Office of Laboratory Animal Welfare (OLAW).

In addition to the incidents that must be reported, I expect continuing communications between ACUC Chairs with the Director, OACU about matters arising within their ICs. Such discussions are informal and augment regular semiannual reports. The Director, OACU will summarize these discussions for me regularly.

In summary, any individual who has concerns related to the use of animals in biomedical research at NIH is encouraged to voice those concerns at whatever level of NIH authority that is appropriate. To that end, I wish to stress that the NIH will not tolerate any reprisal against an individual who has come forward with concerns or allegations of wrong-doing involving the care and use of animals. Such reprisal is prohibited by law and perpetrators are subject to sanctions. Individuals who feel that a personnel action has been taken against them because they reported an apparent violation of animal care and use requirements, should present their case to their supervisor, their IC Director, the NIH Director, the Office of the Inspector General, or the Office of Special Counsel. If individuals allege any form of discrimination, they should file their complaint with the Office of Equal Opportunity.

Please direct questions or comments regarding the intent or contents of this memorandum to me or to the Director, Office of Animal Care and Use.

Michael M. Gottesman, M.D.

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Addressees:
IC Directors
Scientific Directors
IC ACUC Chairs
Animal Program Directors
IC Veterinarians
Animal Facility Managers
NIH IRP Principal Investigators
NIH IRP Animal Users

cc.

Dr. Taylor Dr. Wyatt